Attorney Docket No.: 33677.00700

IN THE SPECIFICATION

Please amend the specification as follows:

Page 4, third full paragraph:

Botulinum type A toxin was obtained in a lyophilized form and reconstituted with

preservative free normal saline for injection at a concentration of 5 LD 50 LD 50 units per 0.1 ml.

One LD 50 LD₅₀ unit is the dose necessary to kill 50% of population of 20-30 gm Swiss-

Webster mice. Effort was made to limit initial exposure to a total dose of less than 50 units so as

to avoid inducing muscular weakness, however, in severe situations, as much as 200 units can be

used.

Page 6, fourth full paragraph – page 7, first paragraph on page:

Total dose received per injection cycle ranged between approximately 10 and 200 LD 50

<u>LD₅₀</u> Units (average 48.3 units), with a maximum of 7.5 units per percutaneous puncture. In

each diagnostic category there was a substantial number of responders, including patients with

trigeminal neuralgia. The responses varied from partial relief of pain (>50% improvement of

pain as stated by the patient) to complete relief of pain. The duration of effect varied from 5-12

weeks, which is consistent with the known duration of action of botulinum toxin for other

indications. No diagnostic category demonstrated any significant difference in response rates,

although many of the patients with trigeminal neuralgia did experience partial responses.

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Page 9, third full paragraph – page 10, first paragraph on page:

A most remarkable category in the presently-described study included patients with trigeminal neuralgia. This syndrome is difficult to treat and has an enormous negative impact on quality of life. The literature is lacking in double blind placebo control trials involving the use of many of the accepted first line systemic medications, such as carbamazepine (Tegretol) (TEGRETOL), phenytoin (dilantin) (DILANTIN), gabapentin (Neurontin) (NEURONTIN), tricyclic antidepressants, and baclofen (see reference 16). The sustained efficacy of phenol,

glycerol, or alcohol injections (reference 17) and thermocoagulation (reference 18) are not well documented. Dysesthesia and corneal numbness represent problematic eye complications

documented. Dysesuresia and cornear numbriess represent problematic eye complications

associated with both thermocoagulation and phenol, glycerol or alcohol injections.

Microvascular decompression has been widely used for treatment of refractory cases with benefit

reported at high percentages in a recently reported series (reference 19). However, attendant

serious complications associated with intracranial surgery limits the application of this technique.

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